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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,401	10/16/2003	Robert M. Abrams	01035.0038-15	1256

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EXAMINER

WYSZOMIERSKI, GEORGE P

ART UNIT	PAPER NUMBER
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1742

DATE MAILED: 09/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/688,401

Applicant(s)

ABRAMS ET AL.

Examiner

George P. Wyszomierski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/16/03 (Continuation Application).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/16/03, 2/23/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. The preliminary amendment filed with this continuation application on October 16, 2003 has been entered. Claims 33-41 are pending.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jervis (U.S. Patent 4,665,906).

Jervis discloses medical devices, such as catheters and cannulas, made preferably of a nickel-titanium shape memory alloy which is in a stable austenite phase under ambient conditions, and which transforms to martensite upon the application of stress; see Jervis column 1, lines 23-40. These materials have a recoverable strain of up to 5%; see Jervis column 3, line 51.

Jervis does not specify the process steps, referred to in product-by-process terms in the instant claims, does not specify the transformation stress recited in instant claims 34 and 35, and does not specify the outer diameter and wall thickness as defined in instant claim 36. These differences are not seen as resulting in a patentable distinction between Jervis and the claimed invention because:

a) With regard to the process steps, it is well settled that a product-by-process claim defines a product, and that when the prior art discloses a product substantially the

same as that being claimed, differing only in the manner by which it is made, the burden falls to applicant to show that any process steps associated therewith result in a product materially different from that disclosed in the prior art. See *In re Brown* (173 USPQ 685) and *In re Fessman* (180 USPQ 524).

b) With respect to the transformation stress, because the material used in the prior art and the claimed invention is the same (superelastic Ni-Ti alloy) it is a reasonable assumption that its physical and mechanical properties would likewise be the same in either the prior art or the claimed invention.

c) With respect to size of the products, both the prior art materials and those as claimed are intended for use in blood vessels in the human body, and the proper size for such materials would be dictated by constraints associated with natural limitations imposed by the size of those blood vessels. These constraints would be identical in the prior art and the claimed invention.

Thus, a prima facie case of obviousness is established between the disclosure of Jervis and the presently claimed invention.

4. Claims 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kugo et al. (U.S. Patent 5,507,766).

Kugo discloses superelastic metal tubes for use in dilatation instruments. The prior art materials are preferably Ti-Ni alloys as claimed and preferably have an outer diameter and wall thickness as presently claimed (see Kugo column 5, lines 38-66). Kugo does not disclose the process steps, referred to in product-by-process terms in

the instant claims, and does not specify the transformation stress recited in instant claims 34 and 35. These claimed features do not distinguish the invention from the Kugo products for reasons as set forth in items 3(a) and (b) supra. Thus, a prima facie case of obviousness is established between the disclosure of Kugo et al. and the presently claimed invention.

5. Claims 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (U.S. Patent 5,573,520).

Schwartz discloses flexible tubular members for use as catheters or catheter sheaths. The prior art tubular members have a wall thickness as presently claimed, and are made of Nitinol (a Ni-Ti alloy) or Elgiloy (a Co-Cr-Ni alloy); see Schwartz column 7, lines 56-66). Schwartz does not disclose the process steps, referred to in product-by-process terms in the instant claims, and does not specify the transformation stress recited in instant claims 34 and 35. These claimed features do not distinguish the invention from the Schwartz products for reasons as set forth in items 3(a) and (b) supra. Thus, a prima facie case of obviousness is established between the disclosure of Schwartz et al. and the presently claimed invention.

6. Claims 33-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 5,341,818, over claims 1-28 of U.S. Patent 5,411,476, over claims 1-19 of U.S. Patent 6,280,539, over claims 1-20 of U.S. Patent 6,461,453, over claims 1-23 of U.S. Patent

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6,638,372, or over claims 1-35 of U.S. Patent 6,682,608. Although the conflicting claims are not identical, they are not patentably distinct from each other because all of the claims in the above patents, as well as the instant claims, are directed to Ni-Ti superelastic tubular structures having the same wall thickness and outer diameter range. These structures are in all cases made of an alloy in a stable austenite phase which transforms to martensite upon application of a specified level of stress. The claims in the issued patents do not specify the precise ranges of cold working and heat treating temperatures as recited in the instant claims. However, the issued claims would encompass products treated as recited in the present claims, and it is not seen what, if any, distinction would result from treating a material in the manner as presently claimed versus one treated as done in the issued patents. Thus, no patentable distinction is seen between the products as defined in the instant claims, and those defined in the claims of the '818, '476, '539, '453, '372, or '608 patents.

7. Claims 37-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent 6,280,539, over claims 1-20 of U.S. Patent 6,461,453, over claims 1-23 of U.S. Patent 6,638,372, or over claims 1-35 of U.S. Patent 6,682,608. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the claims of the prior patents define tubular members having an outer diameter and wall thickness as presently claimed. The materials as claimed in the prior patents are made of an alloy which contains nickel, and may further contain cobalt,

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chromium, platinum and niobium, and the examiner notes that the present claims do not specify any particular amounts of these elements being present. The prior patents do not specify a material cold worked 10-40%. However, such materials would fall within the scope of the claims of the prior patents, and it is unclear what distinction, if any, could be made between the materials as defined in those claims and those defined in the instant claims. Thus, the claimed invention is considered obvious in view of the claims of any of the '539, '453, '372, or '608 patents.

8. Claims 38 and 39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,419,693. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '693 claims define a cylindrical shaped intracorporeal device made of a Co-Cr-Ni-W alloy. While the '693 claims do not specify that these devices have been cold worked, it is unclear what distinction, if any, could be made between the materials as defined in those claims and those defined in the instant claims. Thus, the claimed invention is considered obvious in view of the claims of the '693 patent.

9. Claims 37, 40 and 41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,419,693 in view of any of claims 1-19 of U.S. Patent 6,280,539, over claims 1-20 of U.S. Patent 6,461,453, over claims 1-23 of U.S. Patent 6,638,372, or

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over claims 1-35 of U.S. Patent 6,682,608. As stated supra, the '693 claims define articles made of the same material for the same purposes as those of the present claims. The '693 claims do not recite the outer diameters or wall thicknesses as presently claimed. Each of the '539, '453, '372, and '608 claims indicate that the presently claimed dimensions are typically used in the art of intracorporeal devices for the same purposes as the devices of the '693 claims. Thus, one of skill in the art would not consider the presently claimed devices patentably distinct from the devices as claimed in the '693 patent.


10. The remainder of the art cited on the attached PTO-892 and 1449 forms is of interest. This art is held to be no more relevant to the claimed invention than the art as applied in the rejections, supra.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Wyszomierski whose telephone number is (571) 272-1252. The examiner can normally be reached on Monday thru Friday from 8:00 a.m. to 4:30 p.m. Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King, can be reached on (571) 272-1244. Effective July 15, 2005, all patent application related correspondence transmitted by facsimile must be directed to the new central facsimile number, (571)-273-8300. This new Central FAX Number is the result of relocating the Central FAX server to the Office's Alexandria, Virginia campus.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GPW
August 30, 2005


GEORGE WYSZOMIERSKI
PRIMARY EXAMINER
GROUP 1742